

FDA EDI GATEWAY Overview and Status

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Presentation Outline

- ◆ Release 1.0 Overview
 - Capability
 - Technical Approach
 - “Trading Partner” Agreements
- ◆ “What is needed to trade via the FDA Gateway?”
- ◆ Project Status & Next Steps
- ◆ Questions & Comments



EDI Gateway Release 1.0

Capability

Tactical Objective

- ◆ Receive E2b packages and make available for AERS

Strategic Objectives

- ◆ Implement a production EDI Gateway to serve as a secure central receipt point for the Agency
- ◆ Ensure Version 1.0 is scaleable for broader Agency use
- ◆ Maximize the use of COTS and Standards as much as possible



EDI Gateway Release 1.0

Capability

- ◆ FDA has built an EDI-based Gateway System to Transfer Regulatory Information Electronically via the Internet
- ◆ First FDA “User” is the CDER AERS System For receipt of Post-market Adverse Events
- ◆ Project leverages ICH Standardization Efforts



EDI Gateway Release 1.0

Capability

Key Functionality

- ◆ Gateway receives, authenticates trading partner information, and places file into defined area for AERS retrieval
- ◆ Current Production Release is Receipt-Only
- ◆ Requirements for Two-Way exchange to be implemented in later Releases
- ◆ The Gateway is NOT a receipt point for physical electronic media (Continue to use respective Center document rooms / procedures)



EDI Gateway Release 1.0

Capability

Key Functionality

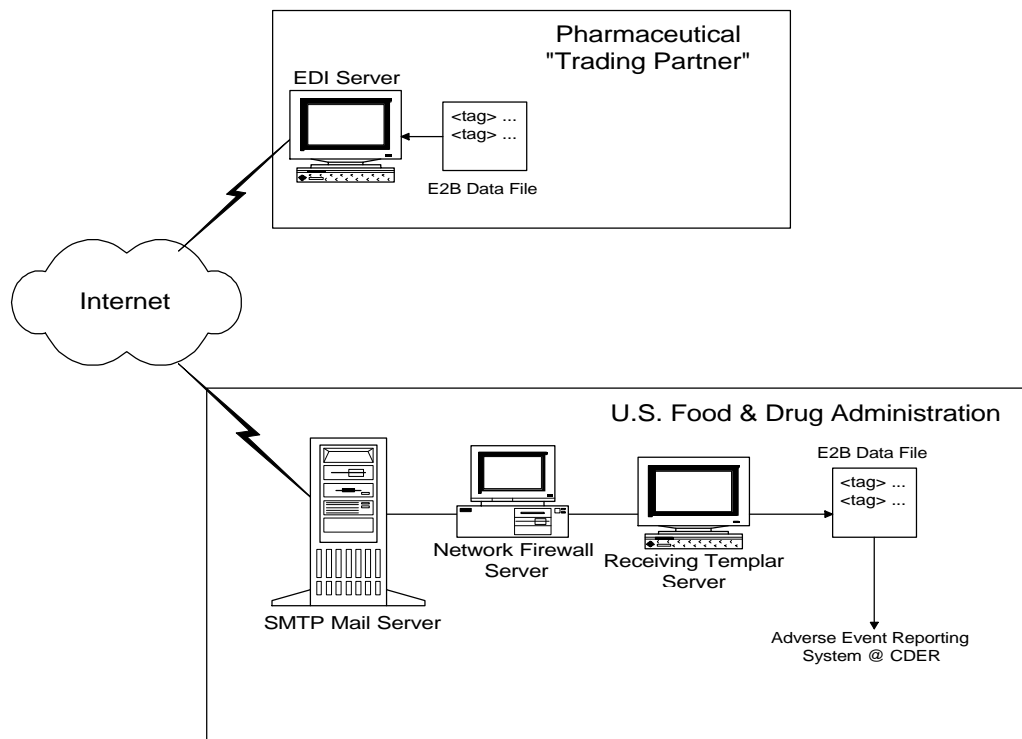
- ◆ Based on ICH M2 Recommendations for ESTRI Gateway
- ◆ Design requirements call for “Least Common Denominator” in order to meet future Agency wide needs
- ◆ Functional compatibility required, not product specific



EDI Gateway Release 1.0

Technical Approach

Conceptual Overview



EDI Gateway Release 1.0

Technical Approach

Templar Interoperability

The Following Companies have passed a 14-test Interoperability Suite conducted by CommerceNet:

- ◆ Actra Business Systems
- ◆ Digital Equipment Corporation
- ◆ Premenos (Templar)
- ◆ Sterling Commerce



EDI Gateway Release 1.0

Technical Approach

- ◆ The Gateway is Not 'Pure' EDI
 - E2b/SGML Embedded in Message
 - Only UNB/UNZ Required
 - Not Really an 'Agreement', but Rather a Mandate
- ◆ Receiving Regulatory Submissions
Electronically does Not Follow 'Pure' EDI Model



EDI Gateway Release 1.0 ***Trading Partner Agreements***

The Agreement Will Specify:

- Gateway Specific Information to Be Exchanged
- Technical Specifications
- ‘Certification’ Process

**The Agreement Will Not Imply Regulatory Compliance. It
Simply Outlines ‘Rules of Usage’ of the Gateway.**

**We estimate the final Release 1.0 Guidance Package
will be completed by the end of February 1998**



EDI Gateway Release 1.0

Trading Partner Agreements

Key Rules of Usage

- ◆ Organizations follow a Certification Process
- ◆ Organizations are only Certified once for trading with the Agency through the Gateway
- ◆ After Certification, FDA Centers / Program Areas decide schedule / content for electronic submissions



EDI Gateway Release 1.0

What do I need to trade via the Gateway?

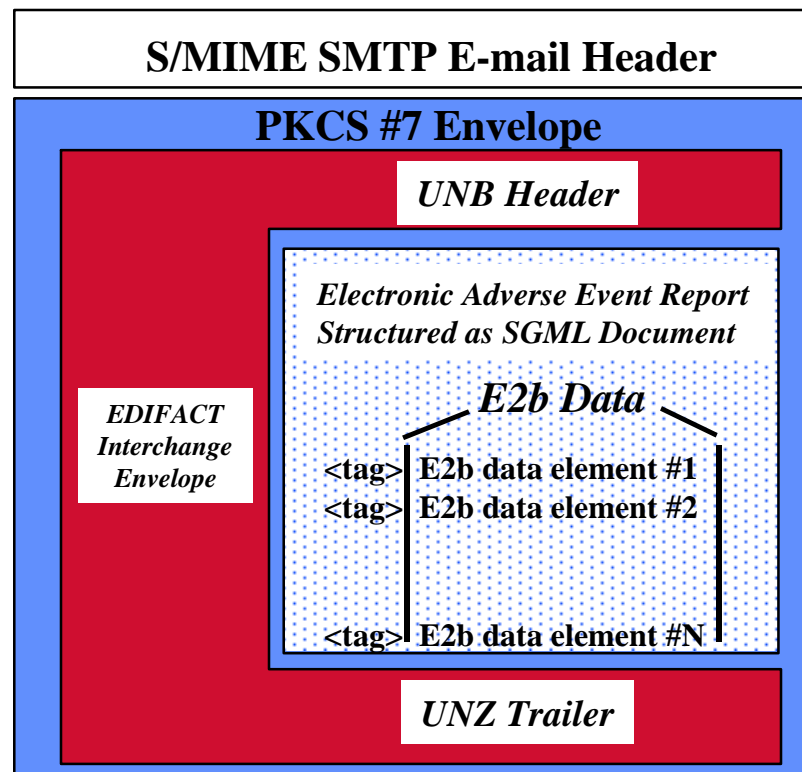
- ◆ Compatibility with Templar 2.1 for UNIX
 - RC2/RC4/DES Encryption
 - S/MIME Transport over Simple Mail Transport Protocol
 - X.509 Certificates, Traded Via E-Mail
 - Generate and Receive EDIFACT AUTACK Message
 - Generate Local Notification if AUTACK Not Received
(Recommended)
- ◆ Ability to Generate EDIFACT UNB/UNZ
'Envelope'



EDI Gateway Release 1.0

What do I need to trade via the Gateway?

Required Message Structure



Gateway Release 1.0 Technical Approach

What do I need to trade via the Gateway?

Typical 'Low End' Configurations

Vendor	Premenos	Harbinger
Product	Templar Desktop for Win95/Windows NT	TrustedLink Commerce
License/Cost	Unlimited Trading Partners \$2,495	Unlimited Trading Partners \$2,795
HW	Pentium PC w/Win95 or Windows NT	Pentium PC w/Win3.1, WFW 3.11 or Win95



EDI Gateway Release 1.0

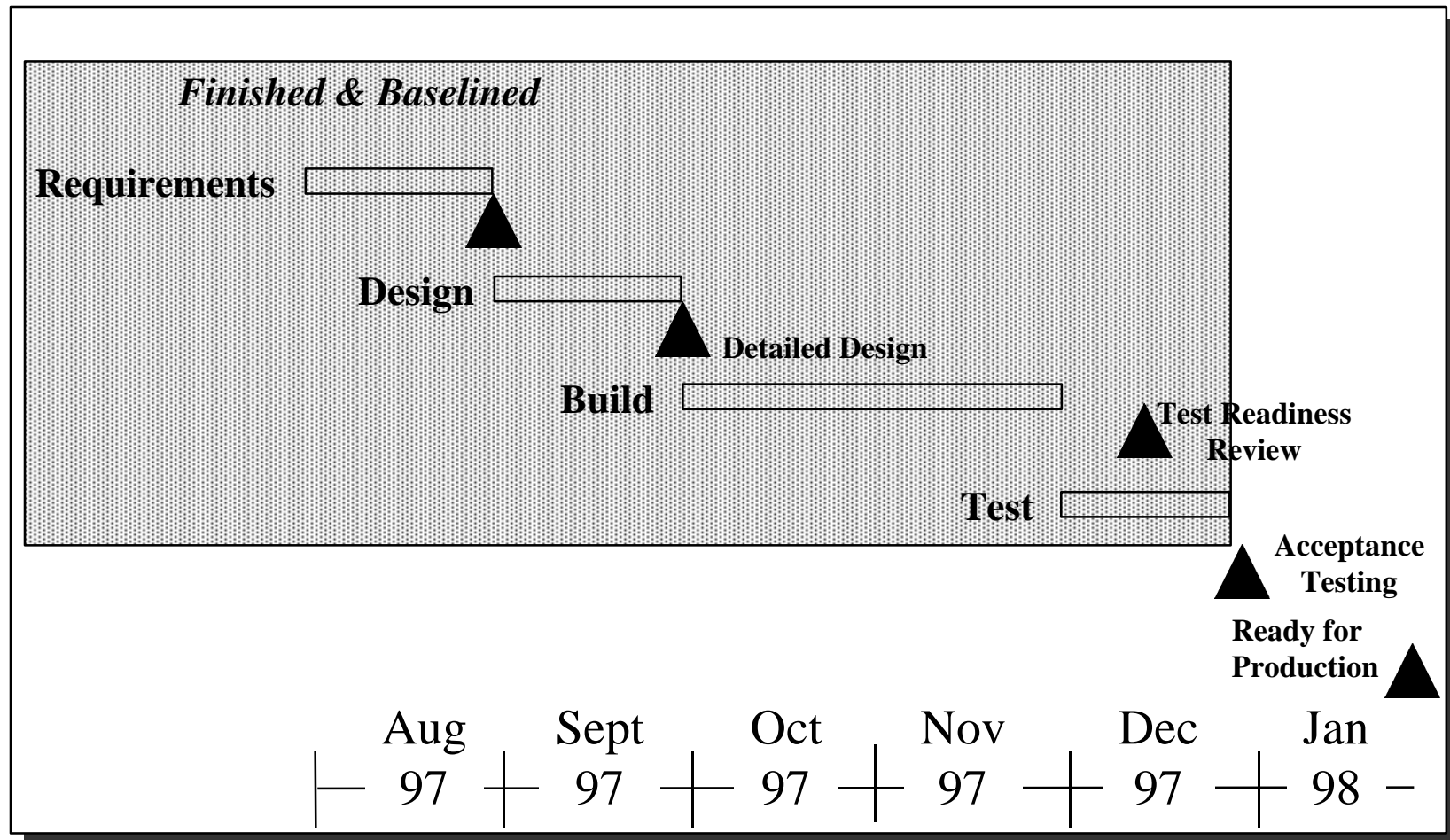
Project Status

- ◆ EDI Server is ready for 'Production'
- ◆ 'Trading Partner Agreement' Drafted
 - Under FDA Review by Internal Agency-wide Working Group
 - Draft guidance information package available for Industry review and comment



EDI Gateway Release 1.0

Project Status



EDI Gateway Release 1.0

Next Steps

- ◆ Obtain Feedback from Regulated Industry
 - Feasible Approach?
 - Single POC for each Company?
 - What types or portions of submissions should we target in future releases? (e.g., IND, NDA, PLA, etc.)
- ◆ Finalize Certification Process
- ◆ Finalize “Trading Partner Agreement” Template
- ◆ Begin Testing with Industry



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